Notices of Exempt Rulemaking

NOTICES OF EXEMPT RULEMAKING

The Administrative Procedure Act requires the *Register* publication of the rules adopted by the state's agencies under an exemption from all or part of the Administrative Procedure Act. Some of these rules are exempted by A.R.S. §§ 41-1005 or 41-1057; other rules are exempted by other statutes; rules of the Corporation Commission are exempt from Attorney General review pursuant to a court decision as determined by the Corporation Commission.

NOTICE OF EXEMPT RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 6. DEPARTMENT OF HEALTH SERVICES COMMUNICABLE DISEASES AND INFESTATIONS

Editor's Note: The following Notice of Exempt Rulemaking was reviewed per the Governor's Regulatory Review Plan memorandum, January 22, 2009 and the continuations issued April 30, June 29 and October 16, 2009. (See the memoranda in this issue on pages 1795 through 1797.) The Governor's Office authorized the notice to proceed through the rulemaking process on August 28, 2009. [R09-95]

PREAMBLE

1. Sections Affected Rulemaking Action

Article 13 New Article R9-6-1301 New Section

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 36-136(A)(7) and (F)

Implementing statute: A.R.S. § 32-1974, as created by Laws 2009, Ch. 41

3. The effective date of the rules:

Date filed with the Office of the Secretary of State: October 5, 2009

4. A list of all previous notices appearing in the Register addressing the exempt rule:

Notice of Public Information: 15 A.A.R. 1472, September 4, 2009

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Karen Lewis, M.D.

Address: Department of Health Services

Office of Immunizations 150 N. 18th Ave., Suite 120

Phoenix, AZ 85007

Telephone: (602) 364-3856 Fax: (602) 364-3198 E-mail: lewisk@azdhs.gov

or

Name: Thomas Salow, Acting Manager

Address: Office of Administrative Counsel and Rules

Department of Health Services 1740 W. Adams St., Room 203

Phoenix, AZ 85007

Telephone: (602) 542-1264
Fax: (602) 364-1150
E-mail: salowt@azdhs.gov

6. An explanation of the rule, including the agency's reasons for the rule, including the statutory citation to the exemption from regular rulemaking procedures:

Arizona Administrative Register / Secretary of State

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On July 10, 2009, the Governor approved a bill related to the administration of immunizations by pharmacists. A.R.S. § 32-1974, as created by Laws 2009, Ch. 41, authorizes pharmacists to administer certain immunizations to adults in compliance with rules adopted by the Board of Pharmacy. A.R.S. § 32-1974, as created by Laws 2009, Ch. 41, also makes the Arizona Department of Health Services (Department) exempt from rulemaking requirements of Title 41, Chapter 6, in establishing and maintaining "a list of immunizations or vaccines that may be administered by a pharmacist only pursuant to a prescription order." The Department is adopting in R9-6-1301 rules specifying those immunizations or vaccines that require a prescription order before being administered to an individual by a pharmacist.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study related to this rulemaking package.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

Not applicable

10. A description of the changes between the proposed rules, including supplemental notices, and final rules:

Not applicable

11. A summary of the comments made regarding the rule and the agency response to them:

Not applicable

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rule:

None

14. Was this rule previously made as an emergency rule? If so, please indicate the Register citation:

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 6. DEPARTMENT OF HEALTH SERVICES COMMUNICABLE DISEASES AND INFESTATIONS

ARTICLE 13. IMMUNIZATIONS OR VACCINES REQUIRING PRESCRIPTIONS FOR PHARMACIST ADMINISTRATION

Section

R9-6-1301. <u>Immunizations or Vaccines Requiring a Prescription Order for Pharmacist Administration</u>

ARTICLE 13. IMMUNIZATIONS OR VACCINES REQUIRING PRESCRIPTIONS FOR PHARMACIST ADMINISTRATION

R9-6-1301. Immunizations or Vaccines Requiring a Prescription Order for Pharmacist Administration

A. In this Section, unless otherwise specified, the following definitions apply:

- 1. "Certified pharmacist" means an individual licensed under A.R.S. Title 32, Chapter 18, who is authorized under A.A.C. R4-23-411 to administer immunizations or vaccines to adults.
- 2. "Immunization" has the same meaning as in A.R.S. § 36-671.
- 3. "Prescription order" has the same meaning as in A.R.S. § 32-1901.
- 4. "Vaccine" has the same meaning as "biological product" defined in 21 CFR 600.3 (April 1, 2008).
- **B.** The following immunizations or vaccines require a prescription order before the immunization or vaccine may be administered under A.A.C. R4-23-411 by a certified pharmacist:
 - 1. Japanese Encephalitis vaccine,
 - 2. Rabies vaccine,
 - 3. Typhoid vaccines, and
 - 4. Yellow fever vaccine.